MV Life, LLC
Chhavy Tep-Cullison
Senior Quality and Regulatory Specialist
Jalex Medical
27865 Clemens Rd. Suite 3
Westlake, OH 44145

April 23, 2026

Re: K252407
Trade/Device Name: OxyGo Portable Oxygen Concentrator (1400-7000)
Regulation Number: 21 CFR 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: Class II
Product Code: CAW
Dated: July 31, 2025
Received: August 21, 2025

Dear Chhavy Tep-Cullison:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252407

Please provide the device trade name(s).

OxyGo Portable Oxygen Concentrator

Please provide your Indications for Use below.

The OxyGo Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, vehicle, and other transport modalities. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Applicant:	MV Life, LLC 2200 Principal Row Orlando, FL 32837
Date:	04/21/2026
Contact Person:	Chhavy Tep-Cullison
Contact Telephone:	(440) 320-4338
Contact Fax:	(440) 933-7839
Device Trade Name:	**OxyGo Portable Concentrator**
Common Name:	Generator, Oxygen, Portable
Device Classification Name:	Portable Oxygen Generator
Regulation Number:	21 CFR 868.5440
Regulatory Class:	Class II
Reviewing Panel:	Anesthesiology
Product Code:	CAW
Primary Predicate Device:	**K230052 – Inogen Rove 6 Portable Oxygen Concentrator**

Device Description:
The OxyGo Portable Oxygen Concentrator is a Class 2, low risk, portable oxygen generator that provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It is used with a nasal cannula to channel oxygen from the device to the patient. The concentrator and the nasal cannula are non-sterile. The OxyGo Portable Oxygen Concentrator is capable of continuous use in a home, institution, vehicle, and various mobile environments. Power options include 100 – 240 V-AC (50-60Hz) power supply, rechargeable battery packs, or a 13.5-15.5 V-DC power cable. The OxyGo Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology; ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. A series of sieve beds, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function. The OxyGo Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient. The design of the OxyGo Portable Oxygen Concentrator has focused on maximizing subsystem efficiencies and miniaturizing components to enable continuous-duty use and to provide minimal weight with battery operation for mobile use.

Indications for Use and Intended Use:
The OxyGo Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, vehicle, and other transport modalities. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.

Summary of Technological Characteristics:

The subject OxyGo Portable Oxygen Concentrator has the same intended use and indications for use as the predicate system. The technological characteristics of the subject system are similar to those of the predicate, and the information provided herein demonstrates that any differences do not impact safety or effectiveness.

Item	Subject Device	Primary Predicate	Equivalence
	OxyGo Portable Oxygen Concentrator	Inogen Rove 6 Portable Oxygen Concentrator (K230052)	
Classification Name	Generator, Oxygen, Portable	Generator, Oxygen, Portable	Substantially equivalent
Regulation	21 CFR 868.5440 (Portable Oxygen Generator)	21 CFR 868.5440 (Portable Oxygen Generator)	Substantially equivalent
Product Code	CAW	CAW	Substantially equivalent
Indications for Use	The OxyGo Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, vehicle, and other transport modalities. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.	The Inogen Rove 6 Portable Oxygen Concentrator provides a high concentration of supplemental oxygen to patients requiring respiratory therapy on a prescriptive basis. It may be used in home, institution, vehicle, and other transport modalities. This device is to be used as an oxygen supplement and is not intended to be life sustaining or life supporting.	Substantially equivalent
Principle of Operation	The OxyGo Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the room. A series of sieve beds, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function. Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle when it is not needed. OxyGo Portable Oxygen Concentrator senses the beginning of the inhalation	The Inogen Rove 6 Portable Oxygen Concentrator uses molecular sieve/pressure swing adsorption technology. Ambient air is drawn through particle filters by a compressor and forced through molecular sieve beds, which adsorb nitrogen and allow oxygen to pass. The airflow is then changed, and nitrogen is desorbed from the molecular sieve, allowing it to adsorb again during the next cycle. Oxygen is collected in an accumulator reservoir. Waste nitrogen is exhausted back into the room. A series of sieve beds, manifolds and precision valves, sensors and embedded software are used to control the cycle to make the system function. Oxygen is delivered to the patient on a pulse dose basis in precise amounts during the inhalation part of the breathing cycle. This conserver technology eliminates waste of unused oxygen at other times	Substantially equivalent

Item	Subject Device	Primary Predicate	Equivalence
	OxyGo Portable Oxygen Concentrator	Inogen Rove 6 Portable Oxygen Concentrator (K230052)	
	cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient.	in the breathing cycle when it is not needed. Inogen Rove 6 Portable Oxygen Concentrator senses the beginning of the inhalation cycle and releases a specified dose of oxygen enriched gas from the accumulator reservoir, through a final filter, into the connected nasal cannula and on to the patient.	
Prescriptive	Yes	Yes	Substantially equivalent
Intended Users	Adult patients requiring supplemental oxygen on a prescriptive basis	Adult patients requiring supplemental oxygen on a prescriptive basis	Substantially Equivalent
Oxygen Delivery Mode	Pulse Dose	Pulse Dose	Substantially Equivalent
Patient/User Interface	• LCD Display to convey information about operating status in numbers and symbols • Alarm Indicator – yellow LED on UIP above Alarm/Warning" triangle symbol that illuminates to indicate abnormal operating conditions in compliance with ISO 60601-1-8 • Breath Detect Notification – Green LED on UIP illuminates when a breath is detected, and an oxygen pulse is triggered • Auditory Speaker – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8 • Battery release latch – Patient removable battery using push latch to release battery then slide off bottom of concentrator • Sieve beds – Users may send device to provider for sieve bed replacement, or users may replace sieves. Sieve beds are user replaceable by pulling the wire handle while depressing the retaining tab to pull the columns out. The replacement columns are installed by pushing them in until the retaining tab snaps into place • Particle Filter – Patient instructed to clean particle filters once per week • Optional accessories - Carry Bag	• LCD Display to convey information about operating status in numbers and symbols • Alarm Indicator – yellow LED on UIP above Alarm/Warning" triangle symbol that illuminates to indicate abnormal operating conditions in compliance with ISO 60601-1-8 • Breath Detect Notification – Green LED on UIP illuminates when a breath is detected, and an oxygen pulse is triggered • Auditory Speaker – Audible beeps are emitted to indicate alarm or status change conditions in compliance with ISO 60601-1-8 • Battery release latch – Patient removable battery using push latch to release battery then slide off bottom of concentrator • Sieve beds – Users may send device to provider for sieve bed replacement, or users may replace sieves. Sieve beds are user replaceable by pulling the wire handle while depressing the retaining tab to pull the columns out. The replacement columns are installed by pushing them in until the retaining tab snaps into place • Particle Filter – Patient instructed to clean particle filters once per week • Optional accessories - Carry Bag, Backpack, Cart, External Battery Charger	Substantially Equivalent

Item	Subject Device	Primary Predicate	Equivalence
	OxyGo Portable Oxygen Concentrator	Inogen Rove 6 Portable Oxygen Concentrator (K230052)	
		• External Battery Charger (EBC) – Optional accessory. Independent battery charger that utilizes an AC/DC power supply. The EBC slides onto the Inogen Rove 6 battery	
Mobile Application	n/a	Inogen Connect Mobile Application – Optional mobile application for viewing device settings, battery information, and current alerts, available for iOS and Android in English, French.	n/a
Operating System	Software monitored	Software monitored	Substantially equivalent
Filter	Air Inlet Filter	Air Inlet Filter	Substantially equivalent
Bluetooth Technology	n/a	Inogen Connect App – BLE Connection to Android or iPhone	n/a
Size	With standard 8-cell battery: 8.0" H, 3.3" W, 7.4" D	With standard 8-cell battery: 8.1" H, 3.3" W, 7.2" D	Substantially equivalent
Components	AC/DC Power Adapter – Utilizes 100 – 240 V-AC (50-60Hz) AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator DC Power Cable – cord and adapter to allow for connection to 13.5 - 15.5 V-DC power cable outlet with cigarette lighter connector and barrel jack connection to concentrator Battery – utilizes an 8-cell lithium rechargeable battery pack Cannula – patient breathes through off-the-shelf cannula attached toa recessed metal cannula barb on the concentrator	AC/DC Power Adapter – Utilizes 100-240V-AC, 50/60Hz AC power supply and cord for power and charging with wall adapter and barrel jack connection to concentrator DC Power Cable – cord and adapter to allow for connection to 13.5-15.0 V-DC outlet with cigarette lighter connector and barrel jack connection to concentrator Battery – utilizes an 8 or 16-cell lithium battery. Cannula – patient breathes through off-the-shelf cannula attached toa recessed metal cannula barb on the concentrator	Substantially equivalent

<table>
<tr><th rowspan="2">Item</th><th>Subject Device</th><th>Primary Predicate</th><th rowspan="2">Equivalence</th></tr>
<tr><td>OxyGo Portable Oxygen Concentrator</td><td>Inogen Rove 6 Portable Oxygen Concentrator (K230052)</td></tr>
<tr><td>Oxygen Output Flow (Pulse Volumes at Flow Settings)</td><td>
<table>
<tr><th>Breaths per Minute</th><th>Setting 1</th><th>Setting 2</th><th>Setting 3</th><th>Setting 4</th><th>Setting 5</th><th>Setting 6</th></tr>
<tr><td>15</td><td>13.3</td><td>26.7</td><td>40.0</td><td>53.3</td><td>66.7</td><td>80.0</td></tr>
<tr><td>20</td><td>10.0</td><td>20.0</td><td>30.0</td><td>40.0</td><td>50.0</td><td>60.0</td></tr>
<tr><td>25</td><td>8.0</td><td>16.0</td><td>24.0</td><td>32.0</td><td>40.0</td><td>48.0</td></tr>
<tr><td>30</td><td>6.7</td><td>13.3</td><td>20.0</td><td>26.7</td><td>33.3</td><td>40.0</td></tr>
<tr><td>35</td><td>5.7</td><td>11.4</td><td>17.1</td><td>22.9</td><td>28.6</td><td>34.0</td></tr>
<tr><td>40</td><td>5.0</td><td>10.0</td><td>15.0</td><td>20.0</td><td>25.0</td><td>30.0</td></tr>
<tr><td>Total Volume/Min (mL/min)</td><td>200</td><td>400</td><td>600</td><td>800</td><td>1000</td><td>1200</td></tr>
</table>
</td><td>
<table>
<tr><th>Breaths per Minute</th><th>Setting 1</th><th>Setting 2</th><th>Setting 3</th><th>Setting 4</th><th>Setting 5</th><th>Setting 6</th></tr>
<tr><td>10</td><td>21.0</td><td>42.0</td><td>63.0</td><td>84.0</td><td>105.0</td><td>126.0</td></tr>
<tr><td>15</td><td>14.0</td><td>28.0</td><td>42.0</td><td>56.0</td><td>70.0</td><td>84.0</td></tr>
<tr><td>20</td><td>10.5</td><td>21.0</td><td>315.5</td><td>42.0</td><td>52.5</td><td>63.0</td></tr>
<tr><td>25</td><td>8.4</td><td>16.8</td><td>25.2</td><td>33.6</td><td>42.0</td><td>50.4</td></tr>
<tr><td>30</td><td>7.0</td><td>14.0</td><td>21.0</td><td>28.0</td><td>35.0</td><td>42.0</td></tr>
<tr><td>35</td><td>6.0</td><td>12.0</td><td>18.0</td><td>24.0</td><td>30.0</td><td>36.0</td></tr>
<tr><td>40</td><td>5.3</td><td>10.5</td><td>15.8</td><td>21.0</td><td>26.3</td><td>31.5</td></tr>
<tr><td>Total Volume/Min (mL/min)</td><td>210</td><td>420</td><td>630</td><td>840</td><td>1050</td><td>1260</td></tr>
</table>
</td><td>Substantially equivalent</td></tr>
<tr><td>Oxygen Delivery Mode</td><td>Pulse dose</td><td>Pulse dose</td><td>Substantially equivalent</td></tr>
<tr><td>Oxygen Purity</td><td>93% (+3/-3%) at all flow rates</td><td>90% - 3%/+6% at all settings (87%-96%)</td><td>Substantially equivalent</td></tr>
<tr><td>Inspiratory Trigger Sensitivity</td><td><20 Pa</td><td><0.12cm/H2O</td><td>Substantially equivalent</td></tr>
<tr><td>Maximum Output Pressure</td><td><20.31 PSI (140 kPa)</td><td>< 28.9 PSI (199.3 kPa)</td><td>Substantially equivalent</td></tr>
</table>

Performance Testing – Non-Clinical:
Substantial equivalence was supported by the results of verification testing to confirm that features and performance of the subject device performs as well as the predicate system, including:

- Electrical Safety and EMC
  - IEC 60601-1:2012
  - IEC 60601-1-2: 2012
  - IEC 60601-1-6:2020
  - IEC 60601-1-8:2012
  - IEC 60601-1-11:2015
  - ISO 80601-2-67:2020
  - ISO 80601-2-69:2020
  - IEC 62133-2
- Biocompatibility
  - ISO 18562-2: 2017 Particulate matter
  - ISO 18562-3:2017 Volatile organic compounds
- Software Verification and Validation
  - Software verification and validation testing were conducted, and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*."
  - IEC62304:2015 Medical device software - Software life cycle processes
- Usability Validation
  - Usability evaluation was conducted and documented according to the recognized consensus standards of IEC 62366-1 and IEC 60601-6, with results demonstrating no critical errors and no specific usability problems

Performance Testing – Clinical:
Clinical testing was not applicable to support a substantial equivalence determination for the subject device.

Conclusion
Based on the indications for use, fundamental technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence and does not raise any additional concerns regarding safety or effectiveness.